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| JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702 | | | EXAMINER PREBILIC, PAUL B | |
| | | | ART UNIT 3738 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,694

Applicant(s)

MATHYS ET AL.

Examiner

Paul B. Prebille

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-33 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 07 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 10/30/03.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

Election/Restrictions

It is noted that claim 19 is drawn to a distinct invention as compared to the other claims of record. A restriction between the product claims and this method of making claim has not been made at this time, but the Examiner reserves the right to do so in the future.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 13 requires a metal coating that is has "substantially no effect on the X-ray transparency." However, metals, in general, are known to have a significant effect on X-ray transparency. For this reason, the presently claimed invention is not enabled because Applicants have not enabled to make a coating of these metals that has substantially no effect on X-ray transparency.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25, 27, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-25, 27, and 29, the dimensions of the surface regularities are not based on any known structure such as radius, cross-section, height, width, length, etc. For this reason, it is clear how to interpret claim language since one does not know whether the dimensions are based upon a full length of some feature or not. Claims 2, 4-19, and 21-25 are rejected along with the base claims because they are dependent upon base claims that contain the indefinite language.

Regarding claim 8, improper Markush language is used that is not clearly closed to the components listed by "consisting of"; see MPEP 2173.05(h). On line 2 of claim 8, "polytherimide" appears to be misspelled, and on line 4, "polysolfone" appears to be misspelled.

Regarding claim 14, "the coating" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Frey et al (US 4,932,969). Frey anticipates the claim language the shape is substantially circular-shaped (see Figures 1 and 2), the radiation permeable material

as claimed is the polyurethane of Frey, the partitions as claimed are partitions (9) of Frey, the perforations as claimed are in the open-celled wire mesh and in partitions (9) of Frey, the cross braces are along axis I-I of Frey (see Figure 2), and the surface irregularities are created by the wire mesh of Frey; see columns 2 and 3.

Regarding claims 31-33, the Examiner has interpreted Frey as having 10 walls or partitions (see Figure 2) such that the first and second partitions are the centermost partitions aligned and running vertically in Figure 2. The remaining 8 walls of Frey make up the first, second, third and fourth walls as claimed. The partitions are aligned but also parallel, giving "parallel" is broadest reasonable interpretation, because they are oriented in the same direction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 11, 12, 20-22, 24, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey et al (US 4,932,969) in view of Van Hoeck et al (WO 07/14377). Frey meets the claim language as explained *supra*, but fails to disclose the irregularities sizes. However, Van Hoeck teaches that irregularities or pores of about 10 microns are preferred in the same art; see page 14, lines 12-22. Therefore, it is the Examiner's position that it would have been obvious to make the pores of Frey about 10

microns for the same reasons that Van Hoeck does the same or in order to prevent implant slippage.

With regard to claims 4, 5, and 22, the size of the perforations are not disclosed by Frey, but they appear to be in the order to magnitude claimed. For this reason, it is the Examiner's position it would have been *prima facie* obvious to make the perforations of Frey of the size claimed since such a size would not effect the function of the final structure; see MPEP 2144.04 (IV), which is incorporated herein by reference.

With regard to claims 11, 12, and 24, since silicone oil and salt solution are known to be X-ray transparent and since they coat the inner surfaces of the hollow body of Frey, the claim language is considered fully met.

Claims 8, 9, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey and Van Hoeck as applied to claims 1-5, 11, 12, 20-22, 24, 27, and 29 above, and further in view of Brantigan (US 5,192,327). Frey fails to disclose the use of the materials claimed. However, Brantigan teaches that such materials were known and used in the art; see column 3, lines 3-18. Therefore, it is the Examiner's position that it would have been obvious to use the materials of Brantigan in the Frey device so as to provide a more supportive structure below the wire meshes.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frey and Van Hoeck as applied to claims 1-5, 11, 12, 20-22, 24, 27, and 29 above, and further in view of Lee et al (US 4,911,718). Frey fails to teach coating the wire mesh with a ceramic as required by the claims. However, Lee teaches that it was known to coat similar implants with the ceramic hydroxyapatite in order to improve ingrowth of bone

thereto. Since Frey also desires bone ingrowth, it would have been obvious to an ordinary artisan to coat the wire meshes of Frey with hydroxyapatite for the same reasons as Lee and Frey.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frey and Van Hoeck as applied to claims 1-5, 11, 12, 20-22, 24, 27, and 29 above, and further in view of Gilding et al (US 4,062,834). Frey fails to disclose the process steps used to make the device. However, Gilding teaches that it was known to use injection molding to make polyurethane implants in the medical and surgical arts; see column 8, lines 20-49. Therefore, it is the Examiner's position that it would have been obvious to use injection molding to form at least parts of the Frey device for the same reasons that Gilding uses the same and in order to mass produce the device quickly and with structural consistency.

Allowable Subject Matter

Claims 6, 7, 10, 15-18, and 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738